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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/626,785 | 07/24/2003 | Michael Lebner | 0156-2006US01 | 1187 |

7590 10/31/2005

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EXAMINER

EREZO, DARWIN P

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary

Application No.

10/626,785

Applicant(s)

LEBNER, MICHAEL

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-13 and 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,329,564 B1 to Lebner in view of US 5,979,450 to Baker et al.

Regarding Claims 1, 9, 19, 27, each of Lebner's anchoring members (5 and 25) have adhesive for sticking to the skin [column 5, lines 45-54; Fig. 3] and connecting members (15 and 35) extending therefrom. "Protective film" is attached to adhesive backed surface of the each anchoring member [column 6, lines 13-15]. Lebner does not disclose a semi rigid tab as set forth in claims 1 or 19.

However, Baker discloses a very similar polymer wound dressing with adhesive for application to skin adjacent an incision [column 1, lines 26-30 and lines 44-46]. Baker teaches a "relatively stiff" handle (22) *protruding from the edge* of "flexible" film (16) [column 8, lines 45-49]. The flexible film/"liner" (16) covers the adhesive (14). Baker explains that in this art often when applying a polymer wound dressing "drape", because of the flimsy nature of the materials used often the polymer becomes wrinkled during the application process and such a shoddy application "may not prevent bacteria on the skin from getting into the wound" [column 2 lines 8-20 and 27-31]. He teaches having a handle—*both* on the "drape" and on the release liner (16) in order to allow

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quick, easy, and wrinkle free application of an adhesive backed wound covering [see also Fig. 1A – Fig. 1C].

It should be noted that the liner of Baker is fully capable of being flipped back onto a portion of the liner while the liner to which the tab is not attached remains fully adhered to the anchoring member. Applicant's own disclosure states that that it is known in the art to provide a crease in the liner (paragraph 29). Moreover, adding a crease to a flat surface in order to provide a fold is well known in the art, such as when a piece of paper is folded to fit into an envelope.

Therefore, it would have been obvious to one having ordinary skill in the art to modify Lebner's wound closure device to have handles—both on the drape part and on the release liner part—in order to allow one surgeon to rapidly and cleanly apply the wound closure device, as taught by Baker. Such handles would extend past the wound edge, as shown in Baker's Fig. 1A.

Regarding Applicant's limitation that the tab extends "beyond the *wound edge*," [emphasis added by Examiner] Examiner considers it a matter of obvious design choice *which edge* of anchoring member (5) [left, right, upper, or lower in Fig. 3 of Lebner] tab (22) extends beyond. As long as the tab extends beyond *one of the edges*, allowing the user to easily flip the tab with their finger, it would not matter which side the tab is located. Therefore, the user could choose the wound edge.

Regarding Claims 2, 4, 20, and 22, the applied prior art reference would meet claim 1 if it had merely one connecting member (37). However, Fig. 3 shows each component (5 or 25) having three connecting members (35 or 15) connected thereto.

Therefore, for example, one of the *second or third connecting members* (35) could be called a "pulling element." Such a pulling element is attached to the adjacent connecting member via the first/second component.

Alternatively, elements (40 and 45) can be considered pulling elements [column 6, lines 1-10]. These pulling elements are removable along serrated lines (17) and are shaped differently than the anchoring members.

Regarding Claims 8 and 26, Lebner discloses making his two-part connector out of an elastic polymeric material reinforced with mesh (for example). Such a spongy, sieve-like material would certainly be capable of having vapor (water particles) pass through it.

Regarding Claims 3, 5, 6, 7, 10, 11, 12, 21, 23, 24, 25, 28-30, and 32, in column 9 line 66 to column 10 line 10, Baker teaches that one film handle may "be of a distinct color, pattern, or have some other feature distinguishing characteristic that would distinguish one handle from the other."

Regarding Claims 13 and 31, Lebner's release liner is capable of being creased, folded, or bent.

With regards to claims 33 and 34, Lebner teaches reinforcements for the device at col. 2, line 60 – col. 3, line 4.

Response to Arguments

3. Applicant's arguments filed 8/24/05 have been fully considered but they are not persuasive.

In response to applicant's argument regarding the Baker reference, it should be noted that the proposed limitation does not read over the recited references. Baker teaches a release liner is fully capable of being flipped back onto a portion of the liner while the liner to which the tab is not attached remains fully adhered to the anchoring member. Applicant's own disclosure states that that it is known in the art to provide a crease in the liner (paragraph 29). Moreover, adding a crease to a flat surface in order to provide a fold is well known in the art, such as when a piece of paper is folded to fit into an envelope. Furthermore, Baker does not teach away from the handle being stiffer than the liner. Baker merely states that it may or may not be stiffer. Baker teaches that it may be made of materials similar to that of handle 18 or the liner (col. 8k line 56-57). Therefore, Baker allows for the configuration of the handle being stiffer than the liner.

With regards to claims 33 and 34, the indication of allowable subject matter is regretted and an action on the merit is presented above. After carefully reviewing the Lebner reference, it became apparent to the new examiner that the reference teaches the limitations in the recited claims.

Conclusion

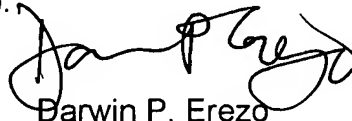
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Darwin P. Erez', is written over the printed name.

Darwin P. Erez
Examiner
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